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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/726,883	11/30/2000	Paul E. Harris	62682/JPW/PT	1468

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EXAMINER

EWOLDT, GERALD R

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 02/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/726,883

Applicant(s)

HARRIS ET AL.

Examiner

G. R. Ewoldt, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,8-11 and 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8-11 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-5, 8-11, and 13 are pending and under examination.
2. Applicant's amendment and remarks, filed 11/08/04, are acknowledged. In view of Applicant's amendments, the previous rejections under the second paragraph of 35 U.S.C. 112 have been withdrawn. Additionally, the previous rejections under the first paragraph of 35 U.S.C. 112 for the introduction of new matter into the claims have also been withdrawn.
3. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 1-5, 8-11, and 13 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As set forth previously, The instant invention is drawn to a method of "reproducibly generating dendritic cells (DCs)" comprising a method of cell culture. Note that the *in vitro* generation of dendritic cells was well known in the art at the time of the invention of the instant claims, however, performing the steps of the instant claims would not necessarily result in a product consisting of said cells given the breadth of the claims, i.e., the lack of specific limitations. As such, the method of the instant claims must be considered highly unpredictable and requiring of undue experimentation.

Step (d) comprises the actual culturing of adherent monocytes to produce DCs. As it is clear (see, for example, the title of the invention) that the method comprises a method of culturing human DC, the incubation of the adherent monocytes would require the inclusion of specific reagents in the incubation, at minimum GM-CSF and IL-4 or IL-7 (see Schuler et al. as set forth in the Background of the Invention).

Applicant's arguments, filed 11/08/04, have been fully considered but they are not persuasive. Applicant argues that the amendment to the claims has overcome the rejection.

It appears that no amendment to part d), the step presumed to comprise the culture of the cells, has been made that includes the culture of monocytes and/or monocyte precursors in the

required cytokines. Indeed, "further processing the contents of the cell culture container" does not necessarily comprise either culturing or "processing" employing cytokines.

5. The following are new grounds for rejection necessitated by Applicant's amendment.

6. Claims 1-5, 8-11, and 13 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) "obtaining blood mononuclear cells through apheresis with monocytes and monocyte precursors being separated substantially from lymphocytes ...[and culturing in media]... said media including at least rh-GM-CSF and at least one of rh-IL-4 or rh-IL-7 reagents" (step a).

B) " further processing the contents of the cell culture container which remain in the container after step (c) and harvesting the dendritic cells from the contents" (step d).

C) In Claim 13, step (b), "incubating the contents of the cell culture container, including the medium and the blood mononuclear cells loaded into the cell culture container in step (a), for culturing, allowing beads with adherent cells attached thereto after incubation to settle, and then expressing off supernatant including nonadherent cells".

Applicant does not indicate that no new matter has been added and does not indicate where support for the new limitations can be found in the specification.

A review of the specification shows that the generic method of the claims is disclosed only briefly starting at line 25 of page 4 through the top half of page 6. Beginning at line 15 of page 6 through line 20 of page 12 is what consists essentially of a specific example. At line 21 of page 12 through the end of the specification is a description of the beads, containers, and quality control employed in the claimed method.

Applicant is advised that individual specific parameters disclosed only in the specific example cannot now be recited in

the generic method of the instant claims without introducing new matter into the claims.

Regarding parameters such as those of part A) above, obtaining blood mononuclear cells through apheresis is only disclosed from G-CSF mobilized donors. Thus, the claims reciting obtaining blood mononuclear cells through apheresis from any donor is broader than the disclosure of the instant specification and thus, comprises the introduction of new matter into the claims. Likewise, the specification teaches only the separation of monocytes and monocyte precursors from red blood cells, lymphocytes, and platelets, and not the separation of monocytes and monocyte precursors from lymphocytes alone. Thus, this limitation again comprises the introduction of new matter, i.e., matter not disclosed in the specification, into the claims.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-5, 8-11, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, specifically:

A) In Claims 1, 2, and 13, the recitation of "obtaining blood mononuclear cells through apheresis with monocytes and monocyte precursors being separated substantially from lymphocytes, and loading blood mononuclear cells into a cell culture container" is vague and indefinite as both of the fractions obtained, i.e., the monocyte and monocyte precursor fraction and the lymphocyte fraction, comprise blood mononuclear cells. Thus, it is unclear which cell fraction is being employed in the claimed method.

9. No claim is allowed.

10. Applicant's amendment or action necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is

not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Inquiries of a general nature may also be directed to the Technology Center 1600 Receptionist at (571) 272-1600.



1/25/18

G.R. Ewoldt, Ph.D.
Primary Examiner
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